

EXHIBIT C

Rachel V. Rose – Attorney at Law, PLLC
P.O. Box 22718
Houston, Texas 77227

To: Scott Simmer, Esq. and Will Powers, Esq.
From: Rachel V. Rose, Esq.
Date: August 14, 2022
Re: HIPAA Analysis Case No. 2:19-cv-02553-JMY (EDPA)

MEMORANDUM

Overview

On March 28, 2022, a 680-page Second Amended Complaint (“SAC”) with Exhibits was filed by Relators’ counsel in *United States of America ex rel. Ellsworth Associates, LLP v. CVS Health Corporation, et al.*, Case No. 19-cv-2553 (E.D. Pa.) (hereinafter “Case”).¹ The Case is premised on allegations of False Claims Act violations in which CVS devised a scheme essentially requiring Medicare Part D beneficiaries to utilize much costlier, multi-source brand-name drugs instead of providing access to generic prescription drugs, which are typically less costly. In turn, CVS increased its profit margins at the expense of Medicare Part D beneficiaries and taxpayers. In particular, the elderly and end stage renal disease (“ESRD”) patients were adversely impacted on a personal level by the increased costs. Instead of upholding its promise to SilverScript prospective members that CVS was acting in the Medicare Part D beneficiaries’ best interests, it betrayed that trust.

The case is out from under seal and working its way through the trial process in the United States District Court for the Eastern District of Pennsylvania.

The Medicare Part D beneficiaries included in the SAC are redacted and identified as “Beneficiary Nos. 1 – 15” in accordance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the related regulation for redacting protected health information (“PHI”), 45 CFR § 164.514 (a), (b), as well as the Federal Rules of Civil Procedure 5.2(a).

On June 16, 2022, McDermott Will & Emery (“MWE” or “Defense Counsel”) sent Baron & Budd, P.C. (“Relator’s Counsel”) a *Demand for Return of Property* premised on an alleged requirement that their client CVS has certain requirements under HIPAA. On June 20, 2022, Relator’s Counsel sent a response informing Defense Counsel that “[b]ecause Ms. Miller retained only a small subset of documents from CVS necessary to pursue a *qui tam* lawsuit, her actions are protected by federal law. Ms. Miller will not return any documents to CVS.”

¹ United States of America ex rel. Ellsworth Associates, LLP shall be referred to “Relator” and CVS Health Corporation and other defendants shall be referred to as “CVS”.

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On August 2, 2022, Mr. Brian Stimson, Esq. sent an email to Mr. Scott Simmer, Esq with four (4) other attorneys cc'd (Subject: RE: Ellsworth/CVS: Call) regarding three open issues: "(1) CVS's renewed request for an accounting of the CVS documents that Ms. Miller took from the company when her employment ended, (2) CVS's request for a demand so that CVS may evaluate the relator's invitation to discuss settlement, and (3) whether the relator will be requesting a status conference from the Court and, if so, for what time frame."

In light of this background, the following four (4) issues, short answers, and analysis of the four issues are examined. In sum, Relator's Counsel should prevail against Defense Counsel on these four issues for the reasons stated herein; however, to reiterate, no guarantee can be provided as to how a court or other entity may opine.

Issues

The following items are potential issues which have either been raised by defense counsel or are potentially implicated because of the respective assertions and/or inquires:

1. Whether or not Relator was within its right and under the protections of HIPAA and the DTSA to utilize information from its previous employer CVS, including PHI, for the purpose of providing it to an attorney and/or the government;
2. Whether or not Baron & Budd, P.C. is considered a "business associate" within the meaning of 45 CFR § 160.103 and whether rev.com is considered a "subcontractor" within the meaning of 45 CFR § 160.103;
3. Whether or not rev.com has adequate technical, administrative, and physical safeguards in place as determined by its disclosures to the public to meet the requirements of various laws to protect the confidentiality, integrity, and availability of consumers and attorneys' sensitive information; and
4. Whether or not defense counsel's attempted use of 45 CFR §164.528 – Accounting of disclosures of protected health information is permissible.

Short Answers

The following are the short answers to the aforementioned issues:

1. **Yes.** The protections given to individuals reporting suspected HIPAA violations or other healthcare fraud are derived from two laws: HIPAA (45 C.F.R. § 164.502(j)(1)) and the Defend Trade Secrets Act of 2016 (Section 7).
2. **No.** Pursuant to 45 CFR §160.308, under the particular facts and circumstances, Baron & Budd, P.C. is not a business associate of CVS and rev.com is not a subcontractor of Baron & Budd, P.C.
3. **Yes.** As stated on its website and in its Rev Client Non-Disclosure Agreement, rev.com has taken adequate steps to ensure the confidentiality, integrity, and availability of all data, and recognizes its obligations under a variety of data privacy and security laws, regulations, and standards, including GDPR and PCI DSS.

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4. No. Defense counsel's attempt to utilize its requirement to provide individuals with an accounting of disclosures is inapplicable to this situation because an exception applies.

Analysis

PHI Can Be Provided to an Attorney and the Government to Report Suspected Healthcare Fraud and/or HIPAA Violations.

The protections provided to individuals reporting suspected HIPAA violations or other healthcare fraud are derived from two laws: HIPAA (45 C.F.R. § 164.502(j)(1)) and the Defend Trade Secrets Act of 2016 (Section 7). Section 164.502(j)(1) expressly states:

(1) Disclosures by whistleblowers. A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

Here, Relator, as a workforce member of CVS, believed and continues to believe in good faith that CVS, a covered entity, engaged in unlawful conduct and the disclosure of PHI was made to both an attorney and in turn a health oversight agency through the United States Department of Justice ("DOJ").

The Defend Trade Secrets Act of 2016, Section 7(b)(1) – "IMMUNITY. – An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that – "(A) is made – (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal."

Here, Relator provided information in confidence and in accordance with the False Claims Act to the Federal Government through representative counsel and the information, which was redacted,

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was filed in a sealed lawsuit. Therefore, neither Relator nor Relator's Counsel are in violation of the law because the express provisions set forth in HIPAA and the Defend Trade Secrets Act of 2016 allow for the PHI and other information to be provided to an attorney, the Federal Government, and/or filed as part of a sealed complaint.

Baron & Budd, P.C. is Not a Business Associate and Rev.com is Not a Subcontractor as Defined by Federal HIPAA.

45 CFT § 160.103 expressly defines a business associate as follows:

Business associate: (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) *Business associate* includes:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

Here, Relator's Counsel did not create, receive, maintain, or transmit PHI for CVS as a function or activity defined in HIPAA. Rev.com did not, in turn, create, receive, maintain, or transmit PHI on behalf of Relator's Counsel as a subcontractor because Relator's Counsel does not meet the definition of a business associate under HIPAA. Despite this, as addressed *infra*, both Baron and Budd, P.C. and Rev.com take their obligations to protect the confidentiality, integrity, and availability of sensitive data seriously.

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Rev.com Confirmed Its Commitment and Legal Obligations to Protect the Confidentiality, Integrity, and Availability of Sensitive Data, Including Attorney Privileged Information and Sensitive Data.

At the bottom of its website, Rev.com has a link to “[security](#)” which provides adequate disclosures about its technical, administrative, and physical safeguards. Specifically, rev.com states the following:

Soc 2 Type II

Rev engages an independent, third-party auditor to perform an annual SOC2 Type II Attestation. Rev’s SOC2 Type II report includes details on the internal controls at Rev designed to protect the security and maintain the availability of our customer’s data. More information on Rev’s SOC2 Type II report can be found here. [NOTE: customers are required to execute a mutual NDA before the SOC2 Type II report is released.]

GDPR [General Data Protection Regulation (EU Law effective May 2018)]

Rev’s services were built with privacy in mind, designed to make it easy for customers to comply with their privacy obligations. More information on how Rev complies with privacy regulations can be found in Rev’s Data Processing Addendum and Privacy Policy.

PCI

Rev maintains PCI compliance as a merchant for payment processing. All credit card payments are facilitated through a third party payment processor. Rev does not store credit card details, only an independent ID associated with the account handled by the payment processor.

All of these items provide adequate assurances of the technical, administrative, and physical safeguards required to protect the confidentiality, integrity, and availability of the data. GDPR and PCI DSS have privacy and security standards that are at a minimum analogous to the HIPAA and Federal Trade Commission requirements because they are premised on either ISO 27001 and/or the National Institute for Standards and Technology (“NIST”) requirements, which are what the United States Government requires of its own agencies and contractors. Therefore, although Relator’s Counsel is not a business associate under HIPAA and Rev.com is not a subcontractor under HIPAA, rev.com has disclosed adequate safeguards and Relator’s counsel took steps to ensure that the entity that it chose as part of its business operations handles sensitive information in a manner that meets standards that apply to a wide variety of laws and industries.

CVS is Not Entitled to Receive Information from Baron & Budd, P.C. Related to 45 CFR §164.528 (Accounting of Disclosures).

45 CFR § 164.528(a) expressly states that

(a) Standard: Right to an accounting of disclosures of protected health information.

(1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in § 164.506;

(ii) To individuals of protected health information about them as provided in § 164.502;

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- (iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in § 164.502;
- (iv) Pursuant to an authorization as provided in § 164.508;
- (v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;
- (vi) For national security or intelligence purposes as provided in § 164.512(k)(2);
- (vii) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5);
- (viii) As part of a limited data set in accordance with § 164.514(e); or
- (ix) That occurred prior to the compliance date for the covered entity.

As analyzed above, Section 164.502(j)(1) permits the disclosures made by Ms. Miller to her attorneys and the Federal Government. Because she meets this requirement, Section 164.528(a)(ii) does not require Relator's Counsel to provide Defense Counsel with an accounting.

Conclusion

Relator's Counsel should prevail on all four (4) issues based on the express text of the law and the supporting documentation.